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Sodium and Potassium Dimethyldithiocarbamate Salts

Amendment to the Ferbam (PC Code 034801) and Ziram (PC Code 034805) Reregistration Eligibility Decisions

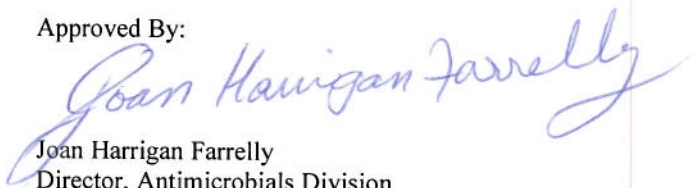
**List D
CASE 2180**

Sodium and Potassium Dimethyldithiocarbamate Salts

**Amendment to the
Ferbam (PC Code 034801) and
Ziram (PC Code 034805) Reregistration Eligibility Decisions**

**List D
CASE 2180**

Approved By:



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June 30, 2009

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC ₅₀	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD ₅₀	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24C of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for Dimethyldithiocarbamate (DDC) Salts and is issuing its risk management decision. This decision amends Reregistration Eligibility Decisions (REDs) issued for other active ingredients in the case (2180) Ferbam (PC Code 034801) and Ziram (PC Code 034805). REDs for these active ingredients were completed in 2005 and 2003, respectively. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products. After considering the risks identified in the revised risk assessments, and mitigation suggestions from interested parties, the Agency developed its risk management decision for uses of DDC Salts that pose risks of concern. As a result of this review, EPA has determined that DDC Salts-containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of DDC Salts. This determination is based on the required data, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that currently registered DDC salts products are eligible for reregistration provided that the risk mitigation and label amendments identified in this RED are implemented. In an effort to simplify the RED, the information presented herein is summarized from more detailed information which can be found in the technical supporting documents for DDC Salts referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at www.regulations.gov (Docket ID #EPA-HQ-OPP-2009-0321). This decision amends Reregistration Eligibility Decisions (REDs) issued for other active ingredients in the case (2180) Ferbam (PC Code 034801) and Ziram (PC Code 034805). REDs for these active ingredients were completed in 2005 and 2003, respectively. These documents are available in the Public Docket at www.regulations.gov [Docket ID # EPA-HQ-OPP-2004-0337 (Ferbam), and Docket ID # EPA-HQ-OPP-2005-0459 (Ziram)].

The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The DDC Salts belong to the dithiocarbamate group of fungicides which have neuropathy as a common toxic effect. In December 2001, EPA concluded, based on the recommendations of the Science Advisory Panel (SAP), that the neuropathy induced by the dithiocarbamates can not be linked to a common mechanism of toxicity (Memorandum titled, The Determination of Whether Dithiocarbamate Pesticides Share a Common Mechanism of Toxicity, From: Marcia Mulkey to Lois Rossi, dated December 19, 2001). Further, EPA has concluded that the dithiocarbamates should not be included in the cumulative assessment of the N-methyl carbamates since they do not share acetylcholinesterase inhibition as their principal mechanism of toxicity. Thus, for the purposes of this reregistration determination, EPA has assumed that the DDC Salts do not share a common mechanism of toxicity with other pesticides.

This document consists of six sections. Section I is the Introduction. Section II provides a chemical overview, a profile of the use and usage of DDC Salts and its regulatory history.

Section III, Summary of DDC Salts Risk Assessments, provides references for the human health and environmental assessments, where the details of the risk assessment can be found. Section IV, Risk Management, Reregistration, and Tolerance Reassessment Decision, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

II. Chemical Overview

A. Regulatory History

The first product containing sodium DDC was registered in 1949, and the first product containing potassium DDC was registered in 1980. For a list of the current products, please see Appendix A. The DDC Salts case consists of two PC codes: 034803 (potassium dimethyldithiocarbamate, or KDDC) and 034804 (sodium dimethyldithiocarbamate, or NaDDC). There are 25 active potassium DDC products and 14 active sodium DDC products. There are no inert uses and no pending registrations.

DDC Salts act as materials preservatives for fuels, metalworking fluids, paints, coatings, adhesives, cloth, and paper/paperboard; they act as antifoulants/slimicides in a variety of liquids including industrial/commercial cooling water, air washer water, sugar mill pulp/process water, marine heat exchangers, gas/oil recovery fluid, industrial wastewater treatment systems, industrial water purification systems, reverse osmosis water systems, and pasteurizer cooling water. Their main uses are as antifoulants in industrial cooling and air washer water systems, as well as pulp and paper mills and gas/oil drilling muds.

Several uses of DDC Salts are pending cancellation as of the publication of this document, including all wood-preserved and paints/coatings uses, as well as preservation of cloth and alginate paste.

B. Chemical Identification

1. Potassium Dimethyldithiocarbamate (KDDC)

Common Name:	Potassium Dimethyldithiocarbamate
Chemical Name:	Carbamic acid, dimethyldithio-, potassium salt, hydrate
Other Name(s):	Carbamodithioic acid, dimethyl-, potassium salt Dimethyldithiocarbamic acid, potassium salt
OPP Chemical Code:	034803
CAS Registry No.:	128-03-0

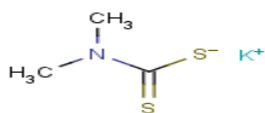
Case Number: 2180

Empirical Formula: C₃H₇NS₂.K

Molecular Weight: 160.33

**Percent Active Ingredient
in Technical-Grade Product:** 50%

Chemical Structure:



Chemical Properties:

Boiling Point: Not required as PAI is a solid

Melting Point: > 300 C with decomposition

Vapor Pressure: Not required as the MP is > 300 C

Solubility in Water: 132 g/100 ml solvent at 20 C

2. Sodium Dimethyldithiocarbamate (NaDDC)

Common Name: Sodium Dimethyldithiocarbamate

Chemical Name: Carbamic acid, dimethyldithio-, sodium salt

Other Name(s): Carbamodithioic acid, dimethyl-, sodium salt;
Dimethyldithiocarbamic acid, sodium salt

CAS Registry Number: 128-04-1

OPP Chemical Code: 034804

Case Number: 2180

Empirical Formula: C₃H₇NS₂.Na

Molecular Weight: 144.22

Manufacturers: R.T. Vanderbilt Co., Kemira Chemicals Inc.,
Alco Chemical

**Percent Active Ingredient
In Technical Grade
Product:** 40%

Chemical Structure:



Chemical Properties:

Boiling Point: Not required as PAI is a solid

Melting Point: > 300 C

Vapor Pressure: Not required as MP is > 300 C; estimated vapor pressure is: 3.7×10^{-8} mm Hg at 25 C.

Solubility in Water: 132 g/100 ml of water at 20 C

C. Use Profile

Information on the currently registered uses of DDC Salts-containing products and an overview of use sites and application methods follows. The detailed table of uses for DDC Salts products eligible for reregistration is contained in Appendix A.

1. NaDDC

Type of Pesticide: Algacide, microbicide/microbistat, fungicide

Use Sites: Materials preservatives for: Adhesives, Paints/Coatings, Fuels/Oils, Metalworking Cutting Fluids, Paper and Paperboard, Textiles/Cordage Products.

Antifoulant/slimicide for industrial process water systems including: Pasteurizer Cooling Water Systems, Air Washer Water Systems, Commercial/Industrial Cooling Water, Pulp/Paper Mill Water Systems, Gas/Oil Drilling Muds/Packer Fluids, Gas/Oil Recovery Injection Water Systems, Gas/Oil Workover and Completion Fluids, Flue Gas Desulfurization Thickeners, Sugar Mills.

Antifouling coatings for: Marine Structures/Equipment (Shipboard Heat Exchangers)

Wood preservatives in: Seasoned Wood Pressure/Thermal Treatment, Wood (veneer), Unseasoned Forest Products Treatment (Sapstain)

Target Pests: Mold/mildew, deterioration/spoilage bacteria, fungi

Formulation Types: liquid or soluble crystals

Methods and Rates of Application:

The methods and rates of application for NaDDC-containing products vary greatly depending on use site. Please refer to Appendix A of this document for more information.

Basic Manufacturer: Akzo Nobel Surface Chemistry LLC, Kemira Corporation, R.T. Vanderbilt Co.

2. KDDC

Type of Pesticide: Algacide, microbicide/microbistat, fungicide

Use Sites: Materials preservatives for: Adhesives, Caulks, Fuels/Oils, Metalworking Cutting Fluids, Paints/Coatings, and Papermaking.

Antifoulant/slimicide for industrial process water systems including: Reverse Osmosis Water Systems, Industrial Water Purification Systems, Air Washer Water Systems, Commercial/Industrial Cooling Water, Pulp/Paper Mill Water Systems, Gas/Oil Drilling Muds/Packer Fluids, Gas/Oil Recovery Injection Water Systems, Gas/Oil Workover and Completion Fluids.

Target Pests: Mold/mildew, deterioration/spoilage bacteria, fungi

Formulation Types: liquid or soluble crystals

Methods and Rates of Application:

The methods and rates of application for KDDC-containing products vary greatly depending on use site. Please refer to Appendix A of this document for this information.

Basic Manufacturer: Buckman Laboratories Inc.

III. Summary of DDC Salts Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for DDC Salts. While the risk assessments and related addenda are not included in this document, they are available from the Agency's Public Docket at www.regulations.gov. The docket identification number is EPA-HQ-OPP-2009-0321. Hard copies of these documents may be found in the OPP public docket which is located in Room S-4400, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

A. Human Health Risk Assessment

1. Toxicity of DDC Salts

The details on the toxicity of DDC Salts can be found in "Hazard Assessment for the Reregistration Eligibility Decision (RED) Document of Sodium Dimethyldithiocarbamate and Potassium Dimethyldithiocarbamate", dated June 2, 2009. These documents are available on the Agency's Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2009-0321).

2. Dietary and Drinking Water Risk Summary

For full information on the dietary and drinking water risk assessment, see "Dietary Risk Assessment for Potassium Dimethyldithiocarbamate for the RED Process," dated July 14, 2009.

3. Occupational and Residential Exposure and Risk Assessment

The occupational and residential exposure assessment considers all potential pesticide exposure, other than exposure due to residues in food or in drinking water. Both occupational and residential exposures of concern were found when examining DDC Salts. For full information on this assessment, see "Sodium and Potassium Dimethyldithiocarbamate: Occupational and Residential Exposure Assessment for the Registration Eligibility Decision (RED)," dated May 14, 2009.

4. Human Incident Data

The Agency consulted the Office of Pesticide Programs' Incident Data System (IDS), the Poison Control Center database, the California Department of Pesticide Regulation, and the National Pesticide Telecommunications Network (NPTN) for incident reports associated with SDDC and/or KDDC.

There were a total of eight reported incidents associated with exposure to end-use products containing SDDC and/or KDDC. Most of the incidents are related to irritation and/or an allergic-type reaction. The most common symptoms reported for cases of dermal exposure were skin irritation/burning, rash, itching, skin discoloration/redness and blistering. The most common symptoms reported for cases of inhalation exposure were respiratory irritation/burning, irritation to mouth/throat/nose, coughing/choking, shortness of breath, dizziness, chemical burn symptoms, and headache.

For full information on incident reports, see “Incident Report for the Reregistration Eligibility Decision (RED) Document of Sodium Dimethyldithiocarbamate and Potassium Dimethyldithiocarbamate”, dated February 5, 2009.

B. Environmental Risk Assessment

The environmental risk characterization is intended to describe the magnitude of the estimated environmental risks for DDC Salts use sites and any associated uncertainties. Aquatic exposures of concern were found when examining DDC Salts. For detailed discussions of all aspects of the environmental risk assessment, see the Environmental Hazards and Ecological Risk Assessment for the Sodium and Potassium Dimethyldithiocarbamate RED, dated May 14, 2008.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing DDC Salts as an active ingredient. The Agency has completed its review of these generic data and has determined that the data are sufficient to support reregistration of all supported products containing DDC Salts.

The Agency has completed its assessment of the residential, occupational, and ecological risks associated with the use of pesticide products containing the active ingredient DDC Salts. The Agency has determined that all DDC Salts-containing products are eligible for reregistration provided that: 1) all risk mitigation measures are implemented; 2) current data gaps and confirmatory data needs are addressed; and 3) label amendments are made as described in Section V. Appendix A summarizes the uses of DDC Salts that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of DDC Salts and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of DDC Salts, the Agency has determined that DDC Salts products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement the risk mitigation measures, submit confirmatory data, and make the label changes identified in this document, the Agency may take regulatory action to address the risk concerns from the use of DDC Salts. If all changes outlined in this document are fully complied with, then no risks of concern exist for the registered uses of DDC Salts and the purposes of this determination. Once an endangered species assessment is completed, further changes to these registrations may be necessary as explained in Section III of this document.

B. Draft Risk Assessment Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders to reach the regulatory decision for DDC Salts. EPA released its preliminary risk assessment for DDC Salts for registrant comment on March 25, 2009. The Agency received several comments from the registrants in two letters during the 30-day public comment period, which closed on April 27, 2009. The comments were mostly editorial in nature; additionally, they addressed two issues regarding the risk assessment's mention of ethylenethiourea (ETU). The registrants claimed that ETU is not a breakdown product of DDC Salts. Finally, the comments corrected an assumption made during the calculation of risk for air washer/industrial cooling water uses, and noted that because the technical grade active ingredient (TGAI) and manufacturing-use product (MUP) are the same in the case of DDC Salts they should not need to resubmit acute toxicity data for DDC Salts.

C. Regulatory Rationale

The Agency has determined that DDC Salts are eligible for reregistration provided that risk mitigation measures are implemented as outlined in this document, additional required data confirm this decision and label changes are made accordingly. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Management

a. Dietary (food) and Drinking Water Risk Mitigation

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic. This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern. The Agency has conducted an indirect food contact dietary exposure and risk assessment for the use of DDC Salts as a materials preservative in adhesives, and paper coatings for repeat use food contact surfaces.

Based on the use patterns of DDC Salts, specifically in paper/paperboard and sugar mills, it is expected that there is potential for indirect food contact; therefore, a dietary risk assessment was performed. However, no dietary risk was found.

Additionally, possible impact on drinking water was considered. DDC Salts were found to be unstable in aerobic water conditions and unlikely to contaminate soil or bioaccumulate in organisms. It is expected that DDC Salts will not impact any source of drinking water; therefore, a drinking water assessment was not conducted. For more information, see “Drinking Water Assessment for DDTC (Potassium/Sodium Dimethyl Dithiocarbamates)”, dated July 8, 2009.

It should be noted that studies were analyzed for the presence of possible degradates such as ethylenethiourea (ETU). No evidence was found of ETU forming solely in the presence of KDDC and SDDC. Additional information can be found in “Dietary Risk Assessment for Potassium Dimethyldithiocarbamate for the RED Process,” dated December 12, 2008.

b. Residential Risk Mitigation

Based on registered use patterns from product labels, it has been determined that exposure to residential handlers or applicators can occur in a variety of residential environments. Additionally, post-application exposures are likely to occur in these settings. The representative scenarios selected by the Agency for assessment were evaluated using maximum application rates as stated on the product labels. The residential exposure assessment considers all potential pesticide exposure, other than exposure due to residues in food and drinking water. Exposure may occur during application for several use patterns including painting/applying via brush/roller and airless sprayer. Post-application exposure may occur from dermal and incidental oral contact with treated lumber (playground equipment or decking) or through incidental oral contact mouthing of treated fabric. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a Margin of Exposure (MOE), which is the ratio of

estimated exposure to an appropriate No Observed Effect Level (NOAEL) dose. Additional information can be found in the “Sodium and Potassium Dimethyldithiocarbamate: Revised Occupational and Residential Exposure Assessment for the Registration Eligibility Decision (RED),” dated May 14, 2009.

i. Residential Handler Risk Mitigation

Residential handler risks were calculated for the short-term duration (1-30 days) because it best represents most homeowner applications. All residential handler risks were not of concern except for the short-term dermal MOE estimated for painters using an airless sprayer at the maximum application rate; MOE = 350. The target MOE for identifying dermal risks of concern is 1000 (10x for interspecies extrapolation; 10x for intra-species variation; and 10x for database uncertainty).

The technical registrant has requested voluntary cancellation of the use of DDC Salts as a paint preservative; the manufacturing label must be amended to remove this use when the cancellation is finalized. This cancellation will eliminate all currently-identified residential handler risks of concern stemming from the use of DDC Salts.

ii. Residential Post-Application Risk Mitigation

Residential post-application risks were calculated for the short-term and intermediate-term duration (1-30 days) for exposure to the treated cloth use because treated clothing can be worn on a daily basis. Both dermal exposures from wearing treated clothing and incidental oral exposures from mouthing treated clothing are anticipated. The dermal MOEs of <1 and 11 are below the target MOE of 1000. The incidental oral MOE is 2 which is below the target MOE.

In addition, there is a potential for child exposure to DDC residues when playing on DDC-treated wood structures such as decks and children’s playsets. Both dermal and incidental oral exposures are anticipated. The dermal MOE of 440 and the incidental oral MOE of 360 are less the target MOE.

The technical registrants have requested voluntary cancellation of all uses of DDC Salts as a wood and cloth preservative; the manufacturing labels must be amended to remove these uses when the cancellation is finalized. These cancellations will eliminate all currently-identified residential post-application risks of concern stemming from the use of DDC Salts.

iii. Aggregate Risk

Based on the use patterns for the DDC Salts, no drinking water assessment was conducted. In addition, the registrants have requested voluntary cancellation of residential scenarios where there were risk concerns (e.g., residential painter, preservation of clothing, and preservation of wood). Therefore, the mitigation measures outlined above for residential risks will eliminate potential aggregate scenarios with risks of concern.

c. Occupational Risk Mitigation

Workers can be exposed to a pesticide through mixing, loading, applying a pesticide, or re-entering treated sites. The DDC Salts are used as a materials and wood preservative. Potential occupational handler exposure can occur in various use sites during the preservation of materials that are used for household, institutional, and industrial uses; and the preservation of wood. As discussed above, each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a MOE, which is the ratio of estimated exposure to an appropriate No Observed Effect Level (NOAEL) dose.

The “preservation of materials” refers to the scenario of a worker adding the preservative to the material being treated (paint, textiles, etc.) through either liquid pour or liquid pump methods. For the preservation of wood at treatment plants and lumber mills, the methods for treatment can vary (pressure/non-pressure), such that multiple worker functions were analyzed.

The representative uses assessed include the following materials preservative and wood preservative incorporation and application methods: mixing and loading of product concentrates for materials preservative incorporation into paint, paper (production), adhesives; application of treated paint (paint brush, roller, and airless sprayer); use of metalworking fluids; and application of protective wood coatings (sapstain control).

i. Occupational Handler Mitigation

Industrial Cooling Water, Oil Production, Pulp and Paper Production, and Pasteurizer Cooling Water (wetable powder formulations)

There is potential for dermal and inhalation exposure when occupational handlers add DDC Salts to Industrial Cooling Water, Oil Production, Pulp and Paper Production, and Pasteurizer Cooling Water systems. The target MOE is 1000 for both dermal and inhalation exposures. The dermal MOEs ranged from 1 – 6000 for these applications. For inhalation exposures, the MOEs ranged from 0 – 2000. To mitigate the risks of concern from the use of wettable powder products, water soluble packaging must be used.

Metalworking Fluids

There is a potential for dermal and inhalation exposure when a machinists use metalworking fluids treated with DDC Salts. This route of exposure occurs after the chemical has been incorporated into the metalworking fluid as a preservative and a machinist uses the fluid during normal machining operations. The dermal exposure was estimated using the film thickness approach and the resulting dermal MOE is 1200, where the target MOE is 1000. The inhalation exposure was estimated using the OSHA PEL approach and the resulting MOE is 2800, where the target MOE is 1000.

While there are no risks of concern pertaining to the metalworking fluids use, the Agency needs confirmatory cancer studies to support metalworking fluids uses where workers may be chronically exposed.

Pressure-Treated Wood and Sapstain

SDDC may be used to pressure treat wood used for decks, buildings, fences, poles, etc., in accordance with two labels (1022-577 and 31910-21). These exposures were assessed using data from a chromated copper arsenate (CCA) exposure study (MRID 455021-01) that was sponsored by Arsenical Wood Preservative Task Force of the American Chemistry Council. The resulting inhalation MOEs range from 400 to 7600 and are of concern for two scenarios because they are less than the target MOE of 1000. The dermal MOEs range from 19 to 2200 and are of concern for most of the scenarios because they are less than the target MOE of 1000.

DDC Salts-specific exposure data are not available for assessment of sapstain treatment occupational exposures. Therefore, this assessment relies on surrogate data from a sapstain treatment worker exposure study (MRID 455243-04) where DDAC was used. The measured DDAC exposure values were normalized by the treatment solution concentration used at each of the 11 facilities in the sapstain treatment exposure study. The resulting inhalation MOEs range from 100 to 5300; the MOE of 100 for the clean-up crew is of concern because it is less than the target MOE of 1000. The dermal MOEs range from 47 to 5300 and are of concern for all of the scenarios except dry wood operations. The lowest dermal MOE of 47 is also for the clean-up crew. The Sapstain Industry Group (SIG) has recently completed additional worker exposure monitoring and the study report (MRID 476183-10) has just been submitted to the EPA. This study has not yet been reviewed. After the review is completed, and if it is considered appropriate, it may be used to refine the worker risks.

As stated above, the technical registrants have requested voluntary cancellation of all uses of DDC Salts as a wood preservative including sapstain control; the manufacturing labels must be amended to remove these uses when the cancellation is finalized.

ii. Occupational Post-Application Risk Mitigation

No occupational post-application exposures are assumed to occur for DDC Salts; all post-application exposures from the DDC Salts are expected to occur in a residential setting. These exposure scenarios were discussed above.

2. Environmental Risk Management

Sodium and potassium dimethyldithiocarbamate salts are registered primarily as material preservatives and for control of bacteria, fungi, and algae in industrial processes and water systems. Material-preservative uses include adhesives, caulks, fuels, metalworking fluids, paints, paper, and textiles. The primary uses in industrial processes and water systems are in air washer systems, water purification systems, cooling waters, drilling fluids, and in recovery injection water systems. Sodium dimethyldithiocarbamate also is used as an antifouling coating in shipboard seawater heat exchangers (closed system) and as a wood preservative (pressure and antisapstain treatment) for wood used for decking, buildings, fences, poles, plywood, and other wooden items.

Environmental exposure levels from wood preservative applications may be of concern for organisms exposed to leachate or runoff. Therefore, an ecological risk assessment is conducted for the wood preservative uses. For additional information on the ecological risks associated with the DDC Salts use, please see the assessment titled “Environmental Hazards and Ecological Risk Assessment for the Sodium and Potassium Dimethyldithiocarbamate RED,” dated January 14, 2008.

Aquatic

Sodium dimethyldithiocarbamate has a potential to reach the aquatic environment due to movement of leachate from treated wood. Therefore, EECs are modeled for treated wood used for docks; for antisapstain treatment; and for wood treated by pressurized spray used for houses, fences, decks, and transmission poles.

Listed (i.e., endangered and threatened) and nonlisted freshwater invertebrates are at acute risk from exposure to sodium dimethyldithiocarbamate leached from wood in docks. Listed and nonlisted freshwater fish are at acute risk at low water volume (1 acre foot), and listed fish also are at risk at 6 to 12 acre feet of water. For antisapstain application, both listed and nonlisted freshwater invertebrates are at risk for the three dilution rates modeled, with the RQ being highest at the lowest dilution rate.

Listed and nonlisted saltwater invertebrates are at acute risk from exposure to sodium dimethyldithiocarbamate leached from wood in docks in saltwater environments (Table 14). Listed saltwater fish are at acute risk only at a low volume of receiving water (1 acre foot). For antisapstain application, both listed and nonlisted saltwater invertebrates are at risk for the three dilution rates modeled (Table 15). Because the LOC is not exceeded, acute risk to fish is presumed to be minimal. However, the registrants have requested voluntary cancellation of the DDC Salts pressure treatment and sapstain treatment for wood. This will mitigate all ecological concerns for the DDC Salts.

Terrestrial

Because sodium dimethyldithiocarbamate is only slightly to practically nontoxic to birds and is practically nontoxic to mammals, minimal acute risk is presumed from its use as a wood preservative. Toxicity data are not available to assess risk to honey bees. However, if use of treated wood is prohibited in bee hives (see Section V, Label Changes Summary Table), minimal exposure and risk are presumed. As mentioned previously, the registrants have requested voluntary cancellation of the DDC Salts pressure treatment and sapstain treatment for wood. This will mitigate all ecological concerns for the DDC Salts.

3. Other Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all manufacturing use products containing DDC Salts. For the specific labeling statements and a list of outstanding data, refer to Section V of this document.

4. Listed Species Considerations

a. The Endangered Species Act

Section 7 of the Endangered Species Act (ESA), 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. § 402.02.

To comply with subsection (a)(2) of the ESA, EPA's Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly appreciably reduce the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). If any of the Listed Species LOC Criteria are exceeded for either direct or indirect effects in the Agency's screening-level risk assessment, the Agency identifies any listed or candidate species that may occur spatially and temporally in the footprint of the proposed use. Further biological assessment is undertaken to refine the risk. The extent to which any species may be at risk determines the need to develop a more comprehensive consultation package as required by the ESA.

For certain use categories, including all current DDC Salt uses other than wood preservative uses, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, p 81). Uses in these categories do not undergo a full screening-level risk assessment and are considered to fall under a no effect determination.

The assessment for wood preservative uses indicates that there is a potential for sodium dimethyldithiocarbamate exposure of listed freshwater and saltwater aquatic species and that a more refined assessment is warranted, to include direct, indirect and habitat effects. However, as discussed previously, the registrants for the DDC Salts have requested voluntary cancellation of its use as a wood preservative and for sapstain control; therefore, no additional risk assessment or risk mitigation measures are needed.

b. General Risk Mitigation

DDC Salts end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing DDC Salts specific to federally listed species, the Agency needs to address potential risks from other

end-use products. Therefore, the Agency requires that users adopt all listed species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting listed species risk mitigation measures, the more stringent measure(s) should be adopted.

V. What Registrants Need to Do

The Agency has determined that DDC Salts are eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision; (ii) label amendments are made; and (iii) risk mitigation measures identified in this document are adopted (Section IV). To implement this decision, the registrant must amend their product labeling to incorporate the label statement set forth in the Label Changes Summary Table in Section B below (Table 1). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of DDC Salts has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory data requirements. A generic data call-in (DCI) will be issued at a later date.

While there are no risks of concern pertaining to the metalworking fluids use of DDC Salts, the Agency needs a confirmatory cancer studies for all metalworking fluids uses where workers may be chronically exposed. This will include a two-generation reproduction study and a combined chronic toxicity/carcinogenicity study.

Previously-submitted SDDC studies on reproduction and fertility effects (870.3800) (MRID 42905, 82096), chronic toxicity in rats (870.4100) (MRID 82096), and chronic toxicity in dogs (870.4100) (MRID 82905) were considered inadequate for this risk assessment because they were conducted with the chemical Vancide 51, an end use product. Vancide 51 is made up two active ingredients, which is not considered appropriate for testing the effects of one active ingredient.

The study used to derive the inhalation endpoint had a very wide dose range of 0, 0.2, 2 and 100 mg/kg/day which resulted in the 50-fold difference between the LOAEL of 100 mg/kg/day and the NOAEL of 2 mg/kg/day. The target MOE is 1000 instead of 100 because it includes an additional factor of ten to account for database uncertainty. If this factor could be eliminated by the submission of additional data then the number of scenarios that would be considered to be of concern would be greatly reduced. For occupational and residential exposures, the Agency needs additional exposure data, including dermal and inhalation indoor exposure, product use information, and applicator exposure monitoring data reporting, in order to fill this information gap.

For DDC Salts technical grade active ingredient products, the registrant needs to submit the following items:

Table 1. Confirmatory Data Needs for Reregistration of DDC Salts

Guideline Study Name	New OPPTS Guideline No.
Reproduction and Fertility Effects	870.3800
Combined Chronic Toxicity/Carcinogenicity	870.4300
Dermal Indoor Exposure	875.1200
Inhalation Indoor Exposure	875.1400
Applicator Exposure Monitoring Data Reporting	875.1600
Product Use Information	875.1700

2. Labeling for Technical and Manufacturing Use Products

To ensure compliance with FIFRA, technical and manufacturing-use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The Technical and MP labeling should bear the labeling contained in the Label Changes Summary Table below.

Within 90 days from receipt of the generic data call-in (DCI):

1. completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and
2. submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Eliza Blair at (703) 308-7279 with questions regarding generic reregistration.

By US mail:
Document Processing Desk
Eliza Blair
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:
Document Processing Desk
Eliza Blair
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

For end-use products containing the active ingredient DDC Salts, the registrant needs to submit the following items for each product:

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and
2. submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. two copies of the confidential statement of formula (EPA Form 8570-4);
2. a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";
3. five copies of the draft label incorporating all label amendments outlined in Table 13 of this document;
4. a completed form certifying compliance with data compensation requirements (EPA Form 8570-34);
5. if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and
6. the product-specific data responding to the PDCI.

Please contact Eliza Blair at (703) 308-7279 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk
Eliza Blair
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:
Document Processing Desk
Eliza Blair
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. A product-specific data call-in, outlining data requirements, will be sent to registrants at a later date.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in the Label Changes Summary Table.

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy," *Federal Register*, Volume 56, No. 123, June 26, 1991.

a. Label Changes Summary Table

In order to be eligible for reregistration, all product labels must be amended to incorporate the risk mitigation measures outlined in Section IV of the DDC Salts RED. The following table describes how language on the labels should be amended.

Table 2. Label Changes Summary Table		
Description	Amended Labeling Language	Placement on Label
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to fish and aquatic invertebrates. Do not contaminate water when disposing of equipment washwaters. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authorities are notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements
PPE Requirements for All Wettable Powder End-Use Products Intended for Occupational Use	Engineering Controls: This product is not to be used in open pour applications. Water soluble packaging must be used for all wettable powder products.	

VI. APPENDICES

Appendix A. Table of Representative Use Patterns for DDC Salts

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Material Preservatives				
Adhesives	Ready-to-use 1022-563 1965-8	Closed systems for liquid applications.	Add product for concentrations of 0.02-0.2% based on total wet weight of product	None
Caulks	Ready-to-use 1022-563	Closed systems for liquid applications.	Add product for concentrations of 0.03-0.2% based on total wet weight of product	None
Fuels/Oils	Ready-to-use 1022-563 31910-2	Open pour	Add product at rate of 6oz.-2.3 pints per 1000 gal. oil	None
	Manufacturing Use: 1448-381	n/a	n/a	n/a
Metalworking Cutting Fluids	Ready-to-use 1022-563	Open pour	Add product for concentrations of 0.03-0.2% based on total wet weight of product	None
	Ready-to-use 1965-8	Open pour	Add 4.175-8.35 lbs. of product per 1000 gallons of fluid	None
Paper and Paperboard	Ready-to-use 1965-8	Closed systems for liquid applications. Water soluble packaging for	Add 1.65-3.3% product based on weight of sheet	None

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
		wettable powder formulations		
Papermaking	Ready-to-use 1022-563	Closed systems for liquid applications. Water soluble packaging for wettable powder formulations	Add product to material for concentrations of 50-400 ppm w/w	None
Dispersion/Emulsions/ Solutions/Suspensions	Ready-to-use 1022-563	Closed systems for liquid applications. Water soluble packaging for wettable powder formulations	Add product for concentrations of 0.03-0.2% based on total wet weight of product	None
Industrial Processes and Water Systems				
Pasteurizer Cooling Water Systems	Ready-to-use 31910-20	Water soluble packaging for wettable powder formulations	Initial dose: Apply 4.8 oz.-1 lb. of product per 1000 gallons of water Subsequent dose: 0.8-1.6 oz. of product per 1000 gallons of water every 3 days	None
Air Washer Water	Ready-to-use	Water soluble	Initial treatment: Add 3.5-	None

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Systems	527-108 1022-563 1448-70 1448-185 1448-198 1448-202 1448-277 1448-282 1448-283 1448-338 1448-339 1448-389 1448-390 1448-391 1448-392 3862-15 9386-11 10707-25 10707-26 31910-2 31910-11 31910-12 31910-20 44392-5 46622-1 68329-2 68329-3	packaging for wetable powder formulations	128 liquid oz. of product per 1000 gallons of water. Maintenance dose: Add 3.5- 72.5 liquid oz. of product per 1000 gallons of water.	None
	Manufacturing Use: 1448-381 9386-39	n/a	n/a	n/a

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Reverse Osmosis Water Systems	Ready-to-use 1448-70 1448-198 1448-277 1448-282 1448-337 1448-338 1448-339 31910-5 44392-5	Closed systems for liquid applications. Water soluble packaging for wettable powder formulations	Off-line: feed product at concentration of 5-50 fl. oz./1000 gallons of water for 4-8 hrs. On-line: dose product at rate of 1-10 fl. oz./1000 gallons of water for 6-12 hrs.	Not for use in potable water systems
Industrial Water Purification Systems (including Filters, Clarifiers, and Ion exchange Equipment)	Ready-to-use 1448-70 1448-198 1448-277 1448-282 1448-337 1448-338 1448-339 31910-5 44392-5	Closed systems for liquid applications. Water soluble packaging for wettable powder formulations	Off-line: feed product at concentration of 5-50 fl. oz./1000 gallons of water for 4-8 hrs. On-line: dose product at rate of 1-10 fl. oz./1000 gallons of water for 6-12 hrs.	Not for use in potable water systems
	Manufacturing Use: 1448-381	n/a	n/a	n/a
Commercial/Industrial Cooling Water	Ready-to-use 527-108 1022-563 1022-574 1448-70 1448-185 1448-198	Closed systems for liquid applications. Water soluble packaging for wettable	Initial treatment: Add 1-128 liquid oz. of product per 1000 gallons of water. Maintenance dose: Add 1.0-17.9 liquid oz. of product per 1000 gallons	None

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	1448-202 1448-277 1448-282 1448-283 1448-338 1448-339 1448-389 1448-390 1448-391 1448-392 3862-156 9386-11 9386-23 9386-37 10707-25 10707-26 31910-2 31910-5 31910-6 31910-11 31910-12 31910-20 44392-5 46622-1 68329-2 68329-3	powder formulations		
	Manufacturing Use: 1448-381 9386-39	n/a	n/a	n/a

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Industrial Wastewater Treatment Systems	Ready-to-use 1448-70 31910-5	Closed systems for liquid applications. Water soluble packaging for wettable powder formulations	Product dosed to system at rate of 0.5-3 fl. oz./1000 gallons of water Continuous feed: add at rate of 0.1-1 fl. oz./1000 gallons of water	None
	Manufacturing Use: 1448-381	n/a	n/a	n/a
Pulp/Paper Mill Water Systems	Ready-to-use 1022-563 1022-574 1448-70 9386-11 9386-37 31910-2 31910-5 31910-6 31910-11 31910-12 31910-20	Closed systems for liquid applications. Water soluble packaging for wettable powder formulations Drip feed	Add 0.04-6.67 lbs. of product per ton of pulp/paper	None
	Ready-to-use 9386-7 31910-5 31910-6	Closed systems for liquid applications. Water soluble	Intermittent feed: Add 18-30 fl. oz. of product per ton of paper for 2 hours every eight hours Continuous feed: Add 6-20	

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
		packaging for wettable powder formulations	fl. oz. of product per ton of paper on continuous basis	
	Manufacturing Use: 1448-381 9386-39	n/a	n/a	n/a
Gas/Oil Drilling Muds/Packer Fluids	Ready-to-use 1022-563 1022-574 1448-70 1448-85 1448-198 1448-202 1448-337 1448-339 9386-23 31910-2 31910-5 31910-6 31910-11 31910-12 46622-1 68329-2 68329-3	Closed systems for liquid applications. Water soluble packaging for wettable powder formulations	Add product at rate of 0.6-25 gallons/100 barrels of fluid	None

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Ready-to-use 9386-7 31910-20	Closed systems for liquid applications.	Add product at rate of 0.56-15 lbs/barrel	
	Manufacturing Use: 1448-381 9386-39	n/a	n/a	
Gas/Oil Recovery Injection Water Systems	Ready-to-use 1022-563 1448-70 1448-85 1448-185 1448-198 1448-202 1448-337 1448-339 1448-381 9386-7 10707-25 10707-26 46622-1 68329-2 68329-3	Closed systems for liquid applications. Water soluble packaging for wettable powder formulations	Add 0.83-12 fl. oz. of product per 1000 gallons of water	None
	Manufacturing Use:			

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	1448-381 9386-39			
	Ready-to-use 1022-574	Closed systems for liquid applications. Water soluble packaging for wettable powder formulations	Add product at ratio of 6.72-17 pints per 1000 gallons of water	None
	Ready-to-use 31910-2 31910-5 31910-11 31910-12 31910-20	Closed systems for liquid applications. Water soluble packaging for wettable powder formulations	Add at rate of 0.3 oz.-6.7 gallons per 100 bbl. of water	None
Gas/Oil Fracturing Fluid Systems	Ready-to-use 31910-2 31910-20	Closed systems for liquid applications. Water soluble packaging for wettable powder formulations	Add product at rate of 0.3-4.3 lbs. per 1000 gallons	None
Gas/Oil Workover and Completion Fluids	Ready-to-use 31910-2	Closed systems for liquid	Add product at rate of 1-4 quarts per 1000 gallons of	None

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
		applications. Water soluble packaging for wettable powder formulations	fluid	
	Ready-to-use 31910-20	Closed systems for liquid applications. Water soluble packaging for wettable powder formulations	Add product at rate of 0.9-3.6 lbs./1000 gallons of fluid	None
	Ready-to-use 46622-1 68329-2 68329-3	Closed systems for liquid applications. Water soluble packaging for wettable powder formulations	Add product at rate of 1.1-21 gallons per 100 barrels of fluid	None
	Manufacturing Use: 1448-381 9386-39	n/a	n/a	n/a
Flue Gas Desulfurization Thickeners	Ready-to-use 31910-2	Closed systems for liquid	Feed at rate of 50-500 ppm of product at least 1 once per	None

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
		applications. Water soluble packaging for wettable powder formulations	week or as required	
Sugar Mills (Cane and Beet)	Ready-to-use 9386-11 9386-23 9386-37 31910-2 31910-6 31910-11 31910-12	Closed systems for liquid applications. Water soluble packaging for wettable powder formulations.	Add at rate of 0.155-1.24 oz. per minute per 1000 tons of cane ground or 1000 beets sliced per day	None
	Manufacturing Use: 9386-39	n/a	n/a	n/a
Antifouling Coatings				
Marine Structures/Equipment (Heat Exchangers)	Ready-to-use 31910-2	Add	Feed at rate of 3.88 lbs. per 100 tons/hr. of system flow rate	None

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

Guide to Appendix B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #2180 (DDC Salts) covered by this RED. It contains generic data requirements that apply to DDC Salts in all products, including data requirements for which a “typical formulation” is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.
2. Use Pattern (Column 4). This column indicates the use patterns for which the data requirements apply. The following number designations are used for the given use patterns.
 - (1) Agricultural premises and equipment
 - (2) Food handling/ storage establishment premises and equipment
 - (3) Commercial, institutional and industrial premises and equipment
 - (4) Residential and public access premises
 - (5) Medical premises and equipment
 - (6) Human water systems
 - (7) Materials preservatives
 - (8) Industrial processes and water systems
 - (9) Antifouling coatings
 - (10) Wood preservatives
 - (11) Swimming pools
 - (12) Aquatic areas
2. Bibliographic Citation (Column 5). If the Agency has acceptable data in its files, this column list the identify number of each study. This normally is the Master Record Identification (MRID) number, but may be a “GS” number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
<u>PRODUCT CHEMISTRY</u>				
830.1550	61-1	Product Identity and Composition		41612201
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process		41612201
830.1670	61-2b	Formation of Impurities		41612201 42922801
830.1700	62-1	Preliminary Analysis		43554002 41612202
830.1750	62-2	Certification of Limits		41612202 43554002
830.1800	62-3	Analytical Method		43554002
830.6302	63-2	Color		42242301 41612203
830.6303	63-3	Physical State		41612203 42242301
830.6304	63-4	Odor		42916701 41612203
830.7200	63-5	Melting Point		Not required
830.7220	63-6	Boiling Point		Not required

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
830.7300	63-7	Density		42242301 41612203
830.7840 830.7860	63-8	Solubility		41612203 42922801 42242301
830.7370	63-10	Dissociation Constant in Water		Waived
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)		Waived
830.7000	63-12	pH		41612203
830.6313	63-13	Stability		42916701 41612203
830.6317	63-17	Storage Stability		42664601 42270401
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Oral Toxicity Test		42561801 159786 159787 42561802
850.1075	72-1	Acute Freshwater Fish (bluegill)		159785

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
850.1075	72-1	Acute Freshwater Fish (rainbow trout)		42247901 159785 159784
850.1010	72-2	Acute Freshwater Invertebrate (daphnia magna)		42504802 159780
850.1300		Freshwater Invertebrate Life Cycle		Needed
850.1400		freshwater fish early life-stage		Needed
850.3030		Honey/beeswax residues and toxicity of treated wood residues to bees data <i>if bee hives might be constructed of treated wood or if any product is intended for application to a bee hive</i> . The study is a combination of Guidelines 171-4 and 850.3030		Needed
850.4400		aquatic plant growth, vascular plant		Needed
850.5400		aquatic plant growth, algal		Needed
850.4225		seedling emergence, rice		Needed
850.4250		vegetative vigor, rice		Needed
TOXICOLOGY				
870.1100	81-1	Acute Oral – Rat		132382
870.1200	81-2	Acute Dermal – Rabbit		146768
870.1300	81-3	Acute Inhalation – Rat		146768

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
870.2400	81-4	Primary Eye Irritation – Rabbit		105157
870.2500	81-5	Primary Dermal Irritation – Rabbit		105157
870.2600	81-6	Dermal Sensitization		132380
870.3100	82-1a	90-Day Feeding-Rodent		40140101
870.3200	82-2	21/28-Day Dermal Toxicity – Rat		40140101
870.3250	82-3	90-day Dermal Toxicity – Rodent		40830801
870.3465	82-4	90-Day Inhalation – Rat		Needed
870.3700a	83-3a	Developmental Toxicity – rodent		40995101
870.3700	83-3b	Teratogenicity – Rabbit		40995101
870.3800	83-4	Reproduction and Fertility Effects - 2 Generation Repro		Needed
870.4100	83-1a	Chronic Feeding Toxicity – Rodent		Not required
870.4200	83-2a	Oncogenicity – Rat		Not required
	83-2b	Oncogenicity – Mouse		Not required
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity		Needed
870.5100	84-2	Bacterial reverse mutation test		
870.5300		In Vitro mammalian cell gene mutation test		
870.5265	84-2a	Gene Mutation – ames		40899001 40631103

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
870.5385	84-2b	Structural Chromosome Aberration		40899001 40631102
870.5395	84-2	<i>In Vivo</i> mammalian micronucleus test /Mammalian erythrocyte micronucleus test		
870.5450		Rodent dominant lethal assay		
870.5900	84-2	Mammalian cytogenetics (sister chromatid exchange)- hamster		
870.7485	85-1	General Metabolism		Not required
870.7600	85-2	Dermal Absorption		Not required
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2300	133-3	Indoor Surface Residue Dissipation (Dermal Residue Transfer Studies for Textiles/Clothing, Mattress/Mattress Ticking and Carpet Shampoo/Cleaner)		Needed
875.1100		Dermal Outdoor Exposure		Needed
875.1200	233	Dermal Indoor Exposure		Needed
875.1300		Inhalation Outdoor Exposure		Needed
875.1400	234	Inhalation Indoor Exposure		Needed
875.1600		Applicator Exposure Monitoring Data Reporting		Needed

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
875.1700 875.2700		Product Use Information		Needed
875.2800	133-1	Description of Human Activity		Needed
875.2900	134	Data Reporting and Calculations		Needed
ENVIRONMENTAL FATE				
835.2410		Photodegradation in Soil		Needed
835.4100		Aerobic Soil Metabolism		Needed
835.6100		Terrestrial Field Dissipation		Needed
Special		Leaching from Treated Wood		Needed

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room S-4400, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The preliminary risk assessment was initially sent to registrants for comment. EPA then considered comments on the risk assessment and revised the risk assessment and supporting chapters as necessary. The revised risk assessment will be posted in the docket at the same time as the RED.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:

<http://www.regulations.gov>

These documents include:

Preliminary Risk Assessment and Supporting Science Documents (RED Supporting Documents):

- Preliminary Human Health Risk Assessment and Ecological Effects Assessment for the Reregistration Eligibility Decision (RED) of Sodium Dimethyldithiocarbamate and Potassium Dimethyldithiocarbamate. PC Codes 034803, 034804, Case 2180. DP Barcode 359712. Risk Assessment and Science Support Branch (RASSB) Antimicrobials Division (7510P). February 5, 2009, Jonathan Chen, Ph.D., Toxicologist, Risk Assessor.
- Sodium and Potassium Dimethyldithiocarbamate: Preliminary Occupational and Residential Exposure Assessment for the Registration Eligibility Decision (RED). PC Codes 034803, 034804, Case 2180. DP Barcode D359715. Risk Assessment and Science Support Branch (RASSB) Antimicrobials Division (7510P). January 23, 2009, Timothy C. Dole, CIH, Industrial Hygienist, Risk Assessor.
- Preliminary Product Chemistry Science Chapter for Reregistration Eligibility Decision (RED) Process for Sodium and Potassium Dimethyldithiocarbamates (Na/K DDC). PC Codes 034803, 034804, Case 2180. DP Barcode D359713. Regulatory Management Branch II, Antimicrobials Division (7510P). December 18, 2008, A. Najm Shamim, PhD, Chemist, Risk Assessor.
- Preliminary Dietary Risk Assessment for Potassium Dimethyldithiocarbamate for the RED Process. PC Codes 034803, 034804, Case 2180. DP Barcode D359714. Regulatory Management Branch II, Antimicrobials Division (7510P). December 18, 2008, A. Najm Shamim, PhD, Chemist, Risk Assessor.
- Preliminary Hazard Assessment for the Reregistration Eligibility Decision (RED) Document of Sodium Dimethyldithiocarbamate and Potassium Dimethyldithiocarbamate. PC Codes 034803, 034804, Case 2180. DP Barcode D359711. Risk Assessment and Science Support Branch (RASSB) Antimicrobials Division (7510P). February 5, 2009, Jonathan Chen, Ph.D., Toxicologist, Risk Assessor.

Revised Final Risk Assessment and Revised Supporting Science Documents (RED Supporting Documents):

- Revised Human Health Risk Assessment and Ecological Effects Assessment for the Reregistration Eligibility Decision (RED) of Sodium Dimethyldithiocarbamate and Potassium Dimethyldithiocarbamate. PC Codes 034803, 034804, Case 2180. DP Barcode 359712. Risk Assessment and Science Support Branch (RASSB) Antimicrobials Division (7510P). June 27, 2009, Jonathan Chen, Ph.D., Toxicologist, Risk Assessor.
- Drinking Water Assessment for DDTC (Potassium/Sodium Dimethyl Dithiocarbamates). PC Codes 034803, 034804, Case 2180. DP Barcode D359714. Regulatory Management Branch II, Antimicrobials Division (7510P). July 8, 2009, A. Najm Shamim, PhD, Chemist, Risk Assessor.
- Sodium and Potassium Dimethyldithiocarbamate: Revised Occupational and Residential Exposure Assessment for the Registration Eligibility Decision (RED). PC Codes 034803, 034804, Case 2180. DP Barcode D359715. Risk Assessment and Science Support Branch (RASSB) Antimicrobials Division (7510P). May 14, 2009, Timothy C. Dole, CIH, Industrial Hygienist, Risk Assessor.
- Dietary Risk Assessment for Potassium Dimethyldithiocarbamate for the RED Process (amended). PC Codes 034803, 034804, Case 2180. DP Barcode D359714. Regulatory Management Branch II, Antimicrobials Division (7510P). July 14, 2009, A. Najm Shamim, PhD, Chemist, Risk Assessor.
- Product Chemistry Science Chapter for Reregistration Eligibility Decision (RED) Process for Sodium and Potassium Dimethyldithiocarbamates (Na/K DDC) (amended). PC Codes 034803, 034804, Case 2180. DP Barcode D359714. Regulatory Management Branch II, Antimicrobials Division (7510P). July 21, 2009, A. Najm Shamim, PhD, Chemist, Risk Assessor.
- Hazard Assessment for the Reregistration Eligibility Decision (RED) Document of Sodium Dimethyldithiocarbamate and Potassium Dimethyldithiocarbamate. PC Codes 034803, 034804, Case 2180. DP Barcode D359711. Risk Assessment and Science Support Branch (RASSB) Antimicrobials Division (7510P). June 2, 2009, Jonathan Chen, Ph.D., Toxicologist, Risk Assessor.
- Environmental Hazards and Ecological Risk Assessment for the Sodium and Potassium Dimethyldithiocarbamate RED. PC Codes 034803, 034804, Case 2180. DP Barcode D359717. Risk Assessment and Science Support Branch (RASSB) Antimicrobials Division (7510P). January 14, 2009, W. Erickson, Ph.D., Biologist, Risk Assessor.

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Decision (Bibliography)

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FDA, 2003. Sanitizing Solutions: Chemistry Guidance for Food Additive Petitions, January 2003. <Http://www.cfsan.fda.gov>

Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date. See Chapter V of the DDC Salts RED for a list of studies that the Agency plans to require.

Appendix F. Product Specific Data Call-In

The Agency intends to issue a Product Specific Data Call-In at a later date.

Appendix G. Batching of DDC Salts Products for Meeting Acute Toxicity Data Requirements for Reregistration

The Agency will complete the batching at a later date.

Appendix H. List of All Registrants Sent the Data Call-In

A list of registrants sent the data call-in will be posted at a later date.

Appendix I. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site:

<http://www.epa.gov/opprd001/forms/>.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf

8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit

www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit that contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
 - a. 83-3 Label Improvement Program—Storage and Disposal Statements
 - b. 84-1 Clarification of Label Improvement Program
 - c. 86-5 Standard Format for Data Submitted under FIFRA
 - d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
 - e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
 - f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
 - g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

- h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

- 3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
 - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
 - b. EPA Form No. 8570-4, Confidential Statement of Formula
 - c. EPA Form No. 8570-27, Formulator's Exemption Statement
 - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
 - e. EPA Form No. 8570-35, Data Matrix
- 4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
 - a. Registration Division Personnel Contact List
 - b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
 - c. Antimicrobials Division Organizational Structure/Contact List
 - d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
 - e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
 - f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
 - g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

- 1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.
4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition. To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.